



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. 09/183,055 Art Unit: 1644
Applicant: June *et al.* AUG 05 2004 Examiner: Phillip Gambel
Date Filed: November 29, 1998 OFFICE OF PETITIONS Conf. No.: 2710
Docket No.: 36119.125US8 Cust. No.: 23483
Title: Method for Selectively Stimulating Proliferation of CD8⁺ T Cells

CERTIFICATION UNDER 37 C.F.R. § 1.10

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PETITION UNDER 37 C.F.R. § 1.182 TO WITHDRAW A RECORDED TERMINAL

DISCLAIMER

Dear Sir:

Applicants respectfully petition to withdraw the Terminal Disclaimer filed on May 13, 2003 in the above-referenced application over U.S. Patent No. 5,858,358.

To recapitulate, in the Final Office Action dated March 6, 2003 (courtesy copy enclosed), the Examiner imposed a rejection under the judicially created doctrine of obviousness-type double patenting in the above-referenced application over U.S. Patent No. 5,858,358 (*see*, Office Action, page 5, section 8). To overcome this rejection, Applicants filed a Terminal Disclaimer over U.S. Patent No. 5,858,358 as part of the Amendment and Response filed on May 13, 2003.

In the subsequent Notice of Allowability dated August 22, 2003, the Examiner indicated in the section entitled "Reasons for Allowance" that the Terminal Disclaimer over U.S. Patent No. 5,858,358 had been recorded by the Patent Office.

Upon careful reconsideration of the currently pending claims of the instant application and those of U.S. Patent No. 5,858,358, Applicants respectfully submit that the Terminal Disclaimer filed in the instant application over U.S. Patent No. 5,858,358 was erroneously filed. Applicants aver that the Terminal Disclaimer was unnecessary because no obviousness-type double patenting exists between the instant application and U.S. Patent No. 5,858,358. Applicants recognize that a provisional obviousness-type double patenting rejection must rely on a comparison of the claims of the two applications in question. Applicants respectfully contend that the claims of U.S. Patent No. 5,858,358 do not render obvious the claims of the instant application.

The claims of U.S. Patent No. 5,858,358 are directed to:

- (1) a method for inducing a population of CD8⁺ T cells to proliferate, comprising activating a population of T cells; and stimulating a CD9 antigen on the surface of the T cells with a ligand which binds the CD9 antigen, the activating and stimulating steps thereby inducing proliferation of the T cells;
- (2) a method for stimulating a population of CD8⁺ T cell to proliferate, comprising contacting a population of T cells with a first agent which stimulates a TCR/CD3 complex-associated signal in the T cells; and a second agent which stimulates a CD9 antigen on the surface of the T cells;
- (3) a method for stimulating a population of CD8⁺ T cells to proliferate, comprising obtaining peripheral blood leukocytes from an individual; isolating a population of CD8⁺ T cells from the peripheral blood leukocytes by negative selection with a combination of antibodies directed to surface markers unique to the cells negatively selected; contacting the population of CD8⁺ T cells with an anti-CD3 antibody immobilized on a solid phase and a ligand which binds a CD9 antigen present on activated T cells, under conditions appropriate for stimulating proliferation of the T cells; separating the anti-CD3 antibody from the T cells and the ligand; monitoring proliferation of the T cells in response to continuing exposure to the ligand by examining cell

size; and restimulating the T cells with the anti-CD3 antibody and the ligand when T cell size has decreased to induce further proliferation of the T cells; and
(4) a method for inducing a population of CD8⁺ T cells to proliferate, comprising activating a population of T cells; and stimulating the population of T cells with a ligand which binds an antigen on the activated T cells, the antigen being recognized by monoclonal antibody ES5.2D8, the activating and stimulating steps thereby inducing proliferation of the T cells.

In contrast, the instant application is directed to a method for stimulating CD8⁺ T cells within a population of T cells to proliferate, comprising contacting a population of T cells with an anti-CD3 antibody, an anti-CD28 antibody, and an anti-CD9 antibody, under conditions appropriate for proliferation of the T cells; separating the anti-CD3 antibody from the T cells and the anti-CD9 and the anti-CD28 antibody; monitoring proliferation of the T cells in response to continuing exposure to the anti-CD9 and the anti-CD28 antibody; and re-stimulating the T cells with an anti-CD3 antibody and the anti-CD9 and the anti-CD28 antibody when the rate of T cell proliferation has decreased to induce further proliferation of the T cells. There is simply no disclosure in the claims of U.S. Patent No. 5,858,358 to stimulate a population of T cells to proliferate using the combination of anti-CD3 antibody, anti-CD9 antibody and anti-CD28 antibody as required by the instant claims. The ordinarily skilled artisan would readily appreciate that the claims of the instant application and U.S. Patent No. 5,858,358 are different, and not obvious over one another.

For the foregoing reasons, Applicants respectfully request that the Terminal Disclaimer filed in the instant application over U.S. Patent No. 5,858,358 to overcome the double patenting rejection be withdrawn.

Please charge the Petition Fee set forth in 37 C.F.R. § 1.17(h) to our Deposit Account No. 08-0219.

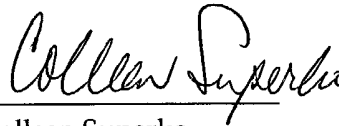
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Petition to Withdraw a Recorded Terminal Disclaimer

The Office of Petitions is invited to telephone the undersigned at the telephone number given below in order to expedite the withdrawal of the Terminal Disclaimer in the instant application over U.S. Patent No. 5,858,358.

Respectfully submitted,

Dated: July 29, 2004



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